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NOV 23 1990

MPI
Pharmacy Services, Inc.
ATTN: Mr. John H. Waterman, Director
Regulatory Affairs and Quality
Assure
2636 South Clearbrook Drive
Arlington Heights, IL 60005-4692

License No.: 48-25915-01MD
Docket No.: 030-30566
EA 90-135

Gentlemen:

Enclosed for your information is a copy of an enforcement action issued to Roche Professional Service Centers, Inc. This enforcement action, for which you attended the enforcement conference, raises questions concerning adequate staffing and corporate oversight of pharmacy activities at Roche Professional Services, Inc., which you have now purchased.

Please review this action and consider whether Amersham needs to take steps to assure that there is adequate staffing, training, and corporate oversight of pharmacy activities so that similar violations will not occur at your facilities. A response is requested to this letter within 30 days.

If you have any questions regarding this matter, please contact John A. Grobe of my staff at (708) 790-5612.

Sincerely,

Carl Paperello for

A. Bert Davis
Regional Administrator

Enclosure: As stated

cc w/o enclosure:
DCD/DCB (RIDS)

bcc w/o enclosure:
J. Lieberman, OE
J. Goldberg, OGL
cc w/enclosure:
J. Gallo, ESQ.

IE 07
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<i>yes referred</i> RIII Grobe/jl 11/21/90	<i>yes</i> RIII Norelius 11/11/90	<i>yes</i> RIII Pederson 11/20/90	RIII Berson 11/23/90	D:OE ** Lieberman 11/ /90	RIII <i>CP</i> Paperello 11/23/90	RIII <i>CP for</i> Davis 11/23/90
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REG3 LIC30
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** J. Lieberman's concurrence received at 7:50 a.m., 11/23/90, during a telephone conversation with C. Weil.
11/23/90



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

November 16, 1990

Docket No. 030-29240
License No. 37-27830-01MD
EA 90-161

Roche Professional Service Centers, Inc.
Bldg. 86, 1st Floor
ATTN: John Kerins
Vice President Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$7,500
(NRC Inspection Report No. 89-001 and Investigation Report 1-89-019)

This letter refers to the NRC safety inspection conducted on October 23 and 31, 1989 at your facility in Philadelphia, Pennsylvania, of activities authorized by NRC License No. 37-27830-01MD. This letter also refers to the subsequent investigation conducted by the NRC Office of Investigations (OI). The report of the inspection and the synopsis of the OI report were forwarded to you on September 21, 1990. During the inspection and investigation, violations of NRC requirements were identified, including a willful violation involving the Facility Manager authorizing a technician to use licensed material when an authorized user was not present, as well as a subsequent failure by the individual to provide accurate information to an NRC inspector. These violations are described in Section I of the enclosed Notice. On October 2, 1990, an enforcement conference was held with you and members of your staff during which these violations, their causes, and your corrective actions were discussed.

With respect to the violations described in Section I of the enclosed Notice, on September 17, 1989, the then Facility Manager authorized a technician at the facility to use licensed material (by drawing doses) when an authorized user was not present. Although the safety significance of the violation was low because the Facility Manager knew that the technician was experienced and technically capable of drawing doses, the Facility Manager's actions constituted a willful violation of regulatory requirements since the Facility Manager knew that the conditions of your license prohibited the use of licensed material when an authorized user was not present. Furthermore, during the NRC inspection on October 23, 1989, the Facility Manager provided inaccurate information to the NRC inspector when she stated to the inspector that she was unaware of any occasions when licensed material was used without an authorized user present.

A license to use radioactive material is a privilege that confers upon the licensee, its officials and employees, the special trust and confidence of the

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public. When the NRC issues a license, it is expected and required that the licensee, as well as its employees and contractors, will strictly comply with all regulatory requirements, and will be completely candid and honest in all dealings with the NRC. Willfully violating regulatory requirements violates that trust and calls into question the licensee's ability to properly perform licensed activities. Such behavior cannot and will not be tolerated. Further, although the OI investigation concluded that there was insufficient evidence from which to conclude that the verbal false statement made by the Facility Manager to the NRC inspector was willful, it is incumbent upon you to ensure that all of your employees understand the need and importance of ensuring that all information provided to the NRC is complete and accurate in all material respects. Therefore, the violations in Section I of the Notice have been classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, (1989).

The NRC recognizes that you have taken disciplinary action against the former Facility Manager (including transferring the individual from the facility and issuing a formal written reprimand); however, to emphasize the importance of your responsibilities for ensuring that (1) licensed activities are conducted in accordance with regulatory requirements, and (2) all information communicated to the NRC (either orally or in writing) is both complete and accurate, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$7,500 for the violations set forth in Section I of the notice.

The base civil penalty amount for a Severity Level III violation is \$5,000. The escalation and mitigation factors set forth in the enforcement policy were considered and the base civil penalty amount for the violations in Section I of the Notice has been increased by 50% because the violations were identified by the NRC. The remaining escalation and mitigation factors were considered and no further adjustment to the base civil penalty is warranted because: (1) your corrective actions, (which included the previously described disciplinary actions against the Facility Manager) while adequate, were narrowly focused on the individual and did not evidence a comprehensive programmatic effort to ensure that all of your employees understand the necessity of strict compliance with regulatory requirements and the need for ensuring that information provided to the NRC is accurate, and therefore, no adjustment on this factor is warranted; (2) while your performance at the time of the previous two inspections was good, it is not appropriate to allow mitigation for this factor in cases involving a willful violation. The other escalation and mitigation factors were considered and no further adjustment was considered appropriate.

In addition to the violations described in Section I of the Notice, other violations were also identified during the inspection and are set forth in Section II of the Notice. These violations involve (1) failure to provide training to licensee personnel in accordance with license conditions, (2) failure to perform required personnel monitoring before leaving the

restricted area, (3) failure to adjust or use a correction factor when dose calibrator constancy exceeded + 5% from the predicted activity, (4) failure to perform dose calibrator linearity tests at 3 month intervals, and (5) failure to restrict the exposure rate from decay wastes in a non-restricted area to background levels. These violations have been classified individually at Severity Level IV and are not the subject of a civil penalty.

While they are not the subject of a civil penalty, the violations described in Section I of the Notice are also of increased concern to the NRC because the number of violations, as well as the fact that several of the violations involved multiple examples, indicate the need for increased and improved management oversight of the licensed program. For example, you had prior notice that your training program was inadequate and that sufficient records to document the training given were not being kept. Specifically, on several occasions prior to this inspection, your consultant identified to you that the training program was not adequate.

In addition, management apparently is not fully cognizant of all applicable regulations and regulatory requirements. For example, although the provisions of 10 CFR Part 35 are not applicable to your activities, management apparently believed that 10 CFR 35.27 allowed work to be conducted under the supervision of an individual who was named as an authorized user on a different NRC license.

You are required to respond to the enclosed Notice and, in preparing your response, you should follow the instructions specified therein. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, your response to this letter should describe the changes that have been made and actions that have been or will be implemented to ensure that (1) licensed activities are conducted in accordance with the license, (2) records of licensed activities, as well as information submitted to the NRC, are complete and accurate, and (3) management is actively involved in, and committed to, compliance with NRC regulatory requirements. This response should also provide your basis for concluding that each person involved in licensed activities understands his or her responsibility and is committed to assure that NRC requirements will be followed and records or information submitted to the NRC will be complete and accurate. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," Part 2 title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Roche Professional Service
Centers, Inc.

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The responses directed by this letter and the enclosure are not subject to the clearance procedure of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,



Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania
State of New Jersey

DISTRIBUTION:

PDR

SECY

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JMTaylor, EDO

HThompson, DEDS

JLieberman, OE

TMartin, RI

JGoldberg, OGC

RBernero, NMSS

RCunningham, NMSS

Enforcement Coordinators

RI, RII, RIII, RIV, RV

FIngram, GPA/PA

BHayes, OI

VMiller, SP

DWilliams, OIG

EJordan, AEOD

OE:JDeI Medico

OE:DBurrier (P File)

OE:Chron

OE:EA

DCS

NOV 19 1990

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Roche Professional Service Centers, Inc.
Philadelphia, Pennsylvania

Docket No. 030-29240
License No. 37-27830-01MD
EA 90-161

During an NRC inspection conducted on October 23 and 31, 1989, at the licensee's facility in Philadelphia, Pennsylvania, and a subsequent investigation by the NRC Office of Investigations, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1989), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below.

I. Violations Assessed A Civil Penalty

- A. License Condition 11A of Facility License No. 37-27830-01MD requires that licensed material be used by or under the supervisor of the individuals named in this License Condition. Condition 12 of this license requires that at least one individual named in Condition 11A of the license be physically present at the authorized place of use whenever licensed material is being used.

Contrary to the above, on September 17, 1989, a technician used licensed material (by drawing doses) when an authorized user listed in Condition 11A of the license was not physically present at the authorized place of use. Additionally, on October 23, 1989, technicians also utilized licensed material when an authorized user listed in Condition 11A of the license was not present at the authorized place of use.

- B. 10 CFR 30.9 requires, in part, that information provided to the Commission by an applicant for a license or by a licensee shall be complete and accurate in all material respects.

Contrary to the above, information provided by the licensee's then Facility Manager during an interview with an NRC inspector on October 23, 1989 was inaccurate in that the Facility Manager answered "No", in response to a question from the inspector regarding whether licensed material was ever used or handled without an authorized user being present. This statement was not accurate in all material respects in that the Facility Manager subsequently admitted to an NRC investigator on February 15, 1990, that she had authorized a technician to draw doses on September 17, 1989 without an authorized user being present in the facility. This statement was material because had NRC been

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aware that the technician had drawn doses on September 17, 1989 without an authorized user being present at the facility, NRC would have taken further regulatory action at that time.

These violations have been classified in the aggregate as a Severity Level III problem (Supplements VI and VII).

Civil Penalty - \$7,500 (assessed equally between the two violations)

II. Violations Not Assessed A Civil Penalty

- A. Condition 23 of License No. 37-27830-01MD requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in the license application dated April 30, 1986.
- i. Item 8 of this application requires that the "Personnel Training Program" contained in Appendix C of Regulatory Guide FC 410-4 (dated August 1985) be followed.

Appendix C requires, in part, that training be provided before an employee assumes duties with or in the immediate vicinity of radioactive materials and that the training be sufficient to ensure that individuals who work in or frequent restricted areas are instructed in the items specified in Section 19.12 of 10 CFR Part 19, and that individuals who work in the immediate vicinity of radioactive materials be informed about radiation hazards and appropriate precautions.

Contrary to the above, as of October 23, 1989, licensee employees who worked in or frequented restricted areas or worked in the immediate vicinity of radioactive materials had not received all the required training to ensure that they were adequately instructed in the items specified in Section 19.12 of 10 CFR, as well as radiation hazards and appropriate precautions as evidenced by the following examples:

- (1) three employees did not receive initial training before they began work;
- (2) approximately nine licensee drivers did not receive training in radiological safety procedures for checking radiopharmaceutical shipment (ammo) boxes in and out; and
- (3) two drivers had not received training in the use of a survey meter.

This is a Severity Level IV violation.

2. Item 10.4 of this application requires that the Procedure for Calibration of Dose Calibrators in Appendix E of Regulatory Guide FC-410-4 be followed.

- a. Item 4.g of Appendix E requires, in part, that if the measured activity of the dose calibrator constancy test varies by greater than $\pm 5\%$ (from the predicted activity), the dose calibrator is to either be adjusted or an arithmetic correction factor is to be used to correct the dosage assays.

Contrary to the above, on nine occasions between April 5, 1989 and September 13, 1989 the measured activity of the constancy test, performed on the cobalt-57 setting for the CRC-12 dose calibrator, varied greater than $\pm 5\%$ from the predicted activity, and the dose calibrator was neither adjusted nor was an arithmetic correction factor used to correct the dosage assays.

This is a Severity Level IV violation.

- b. Item 1 of Appendix E requires that the dose calibrator linearity test be performed at installation and at 3 month intervals thereafter.

Contrary to the above, as of October 31, 1989, the licensee's dose calibrators had not been tested for linearity since June 10, 1989, an interval greater than 3 months.

This is a Severity Level IV violation.

3. Item 9.1 of this application requires, in part, that decayed waste, stored in the storage area above the first floor (non-restricted area), will not exceed background levels.

Contrary to the above, on October 31, 1989, a box of decayed waste located in the non-restricted storage area above the first floor measured 3 mR/hr at the surface, which exceeded the background level of 0.03 mR/hr for this area.

This is a Severity Level IV violation.

4. Item 10.7 of this application requires that the general rules for safe use of radioactive material contained in Appendix H of Regulatory Guide FC 410-4 be followed.

Item 3 of Appendix H requires that hands and clothing be monitored for contamination after each procedure or before leaving the area where radioactive materials are used

Contrary to the above, on October 23, 1989, several licensee employees who prepared shipments of radiopharmaceuticals within the restricted area did not monitor their hands and clothing prior to leaving the area where radioactive materials were used.

This is a Severity Level IV violation.

Pursuant to the provisions of 10 CFR 2.201, Roche Professional Service Centers, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of the notice. The reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order or electronic transfer payable to the Treasurer of the United States, in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1989), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Atomic Energy Act, U.S.C. 2282(c).

The responses noted above (Reply to a Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20055 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

FOR THE NUCLEAR REGULATORY COMMISSION



Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 16 day of November 1990